DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ziehm Imaging GmbH
% Mr. Richard Westrich
Director of Regulatory Affairs and Quality Assurance
Ziehm Imaging, Inc.
6280 Hazeltine National Drive
ORLANDO FL 32822

April 6, 2015

Re: K142740
Trade/Device Name: Ziehm Vision RFD 3D
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO, JAA, JAK
Dated: March 16, 2015
Received: March 16, 2015

Dear Mr. Westrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142740

Device Name: ZIEHM VISION RFD 3D

Indications for Use:

The Ziehm Vision RFD 3D system is intended for use in providing both 2D and 3D medical imaging for all adult and pediatric populations, using pulsed and continuous fluoroscopic imaging.

The device provides 2D medical imaging for fluoroscopy, digital subtraction, and acquisition of cine loops during diagnostic interventional and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumbar regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for Computer-Assisted Surgery procedures.

The device is also intended to provide 3D medical imaging of patients during orthopedic, neurological, intra-operative surgical procedures and where the clinician benefits from 3D visualization of complex anatomical structures, such as but not limited to those of high contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, and where digital image and C-arm positioning data is required for Computer-Assisted Surgery procedures.

The visualization of such anatomical structures assists the clinician in the clinical outcome. At the discretion of a physician, the device may be used for other imaging applications. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use near MRI systems.

Prescription Use _**X**_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

510 (k) Summary

March 31, 2015

In accordance with 21 CFR §807.92 the following 510(k) summary information is provided:

Submitter Address:	Ziehm Imaging GmbH Donaustrasse 31 90451 Nuremberg Germany Phone: + 49.911.2172-219 Fax: +49.911.2172-390
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Secondary Contact Person:	Stefan Fiedler Director QM/RA Ziehm Imaging GmbH Phone: + 49.911. 2172-219 Fax: +49.911.2172-390
Device (Trade Name):	Ziehm Vision RFD 3D
Common /Usual Names:	Mobile Fluoroscopic C-Arm
Classification:	21CFR 892.1650

Regulation Description:	Image-intensified fluoroscopic x-ray system
Device:	Interventional fluoroscopic x-ray system
Product Code:	OWB
Subsequent Classification(s)	21CFR 892.1650
Regulation Description:	Image-intensified fluoroscopic x-ray system
Device:	Image-intensified fluoroscopic x-ray system, mobile
Product Code:	OXO
Subsequent Classification(s)	21CFR 892.1650
Regulation Description:	Image-intensified fluoroscopic x-ray system
Device:	System, x-ray, fluoroscopic, image intensified
Classification Product Code:	JAA
Classification:	21CFR 892.1750
Regulation Description:	Computed tomography x-ray system.
Device:	System, X-ray, tomography, computed
Classification Product Code:	JAK
Predicate Device:	K132904 Ziehm Vision RFD
Decision Date:	12/05/2013
Classification Product Code:	JAA
Classification:	21CFR 892.1650
Subsequent Product Codes:	OWB, OXO

Predicate Device:	K073346 Ziehm Vision^2 FD Vario 3D
Decision Date:	03/12/2008
Classification Product Code:	JAA
Classification:	21CFR 892.1650
Subsequent Product Codes:	OWB, JAK

General Description:

The ZIEHM VISION RFD 3D employs X-rays as its imaging technology for visualizing human anatomy in both 2D and 3D imaging. The X-ray tube in the generator produces X-rays, guided toward the patient under control of the user at the direction of a physician who determines the specific clinical procedure. The images from the system assist the physicians in visualizing the patient's anatomy. This visualization helps to localize regions of pathology and for surgical procedures. The device provides both real-time image capture and post capture visualization and of in vivo surgical procedures and post-surgical outcomes.

The Ziehm Vision RFD 3D mobile fluoroscopy system is a flat panel detector (FD) Computed tomography x-ray system and fluoroscopic X-ray imaging system consisting of two mobile units: a Mobile Stand (C-Arm) and a Monitor Cart/Workstation. The Mobile Stand is comprised of a mono-block high voltage generator, X-ray control, and a C-Profile which is "C" shaped and supports the X-ray generator, and the image receptor Flat Panel Detector (FD).

The device performs both 2D medical imaging and the specialized 4 axes of motorized movement necessary for the 3D imaging. This provides the user/operator the option to use manual or motorized linear and rotational movements of the C- Profile for positioning of the imaging components at various angles and distances with respect to the patient using a control interface, Vision Center, Remote Vision Center or remote Position Control Center.

The motorization of the 4 axes provides the user an alternative for visualizing anatomical structures using a variable iso-centric location. The system working with a variable iso-center allows freely selectable positions of patient anatomy. The variable iso-center and distance control ensures that anatomical structures are safely visualized from different angles without re-adjusting the C-arm or moving the patient. The iso-center is not restricted to orbital movements and can hold this iso-center during angulations and vertical travel using the 4 motorized axes. This same motion control provides the bases for 3D views of the patient anatomy. These 3D views are generated by means of an iterative algorithm.

The system uses the images of a scan captured with relation to a predefined scan center to compute the three-dimensional representation of an object. The 3D views are always displayed on the reference screen of the monitor cart. It is possible to display multiplanar reconstructions, orthogonal or freely selectable sections, and different surface reconstructions.

The Distance Control surface detection integrated around the lower edge of the flat panel detects objects, such as patients. When the flat panel approaches an object, the device reduces speed, slowing the motorized movement. The movement stops immediately before entering a defined safety zone.

The mobile stand supports the optional wireless footswitch for optimum positioning for the surgeon by removing the cable on the floor.

The Monitor Cart is a mobile platform that connects to the Mobile Stand by a cable, and which integrates the LCD flat panel display monitors, 2D image processing, Optional 3D image processing, user controls and image recording devices. Interfaces provided for optional peripheral devices such as external monitors, thermal video printers, wireless video display, wireless video server, injector connection and image storage devices (USB, DVD) and DICOM fixed wired and wireless network interfaces.

Indications for Use: The Ziehm Vision RFD 3D system is intended for use in providing both 2D and 3D medical imaging for all adult and pediatric populations, using pulsed and continuous fluoroscopic imaging.

The device provides 2D medical imaging for fluoroscopy, digital subtraction, and acquisition of cine loops during diagnostic interventional and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumbar regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for Computer-Assisted Surgery procedures.

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Summary of Technological Characteristics:

The Ziehm Vision RFD 3D is based on the Ziehm Vision RFD K132904 including the major system control, x-ray generator, Pulsed fluoroscopy, image detector, 4 Axes motorization, software, with imaging workstation upgraded to integrate the 3D image capture and control functions from our Ziehm Vision^2 FD Vario 3D K073346. The subject device employs the same fundamental scientific technologies, as the predicate devices for system controls, full DICOM compatibility, and intuitive graphical user interface. The technological comparison chart in Section 12, of this premarket submission reveals that the proposed device shares the technological characteristics performed by the predicate devices.

The following table compares the dominant performance data of the subject device with the predicate devices to substantiate equivalence of the subject device and predicate devices.

Features/Technology	Subject Device Ziehm Vision RFD 3D (K142740)	Predicate Device Ziehm Vision RFD (K132904)	Predicate Device Ziehm Vision^2 FD Vario 3D (K073346)
Mobile fluoroscopic c-arm	Yes	Yes	Yes
Product Codes	OWB, OXO, JAA, JAK	OWB, JAA, OXO	JAA, OWB, JAK
User interface touch control panel	Yes, same design	Yes, same design	Yes, same design
X-ray generator and tube housing assembly monoblock technology	Yes, same monoblock design rotating anode	Yes, same monoblock design rotating anode	monoblock design Fixed anode tube
KV Range 40-120 kV	Yes	Yes	40-110 kV Opt 120 kV
Max power output	25 kW Optional 20 kW or 7.5 kW	25 kW Optional 20 kW or 7.5 kW	2.02 kW
Plused fluoroscopy	7.5 kW 1.5-75mA	7.5 kW 1.5-75mA	1.5-20mA

	20 kW 1.5-200mA 25 kW 1.5-250mA	20 kW 1.5-200mA 25 kW 1.5-250mA	
X-ray tube	Rotating anode 0.3, 0.6 focal spot	Rotating anode 0.3, 0.6 focal spot	Stationary anode 0.6 focal spot
Collimator/beam limiter asymmetrical shutters	Yes, same design	Yes, same design	Yes, same design
Virtual collimation	Yes, same design	Yes, same design	Yes, same design
X-ray detector(FPD) Amorphous silicon	Yes, same design 20 cm x 20 cm or 30 cm x 30 cm	Yes, same design 20 cm x 20 cm or 30 cm x 30 cm	Yes, same design 20 cm x 20 cm
FPD Matrix size 20 x 20cm 30 x 30cm FPD's same panel technology.	20 cm x 20 cm 1024x1024 pixels or 30 cm x 30 cm 1536 x 1536 pixels	20 cm x 20 cm 1024x1024 pixels or 30 cm x 30 cm 1536 x 1536 pixels	20 cm x 20 cm 1024x1024 pixels
AERC Dose control system	Yes, same design kV/mA curve types Use of all three	Yes, same design kV/mA curve types Use of only two	Yes, same design kV/mA curve types Use of only two
Image data port for navigation system	Yes, same design Export of image data and parameters	Yes, same design Export of image data and parameters	Yes, same design Export of image data and parameters
Manual and motorized axes of movement	Yes, both manual and motorized 4 axes of movement	Yes, both manual and motorized 4 axes of movement	Yes both manual and motorized 3 axes of movement
Image Post Processing 2D	Yes, same design	Yes, same design	Yes, same design
3D Imaging Workstation With Post Processing	Yes, uses same 3D Image Workstation	No 3D Image Capture	Yes, uses same 3D Image Workstation
3D Reconstruction Algorithm	Yes	No 3D Workstation	Yes
DICOM functionality including RSDR	Yes, same design	Yes, same design	Yes, same design
Monitors Dual 19" TFT Flat Screen Displays	Yes, same design	Yes, same design	Yes, same design
Vision Center Graphical user interface touch panel	Yes, same design	Yes, same design	Yes, same design

Summary of Non-Clinical Test Data:

Ziehm Vision RFD 3D is based on the direct modifications to a cleared predicate device Ziehm Vision RFD (K132904); The Ziehm Vision RFD 3D design changes were completed in accordance with Ziehm Imaging GmbH Quality Management System Design Controls and Engineering, standards compliance, and Verification and Validation testing were successfully conducted. Tests were performed on the Ziehm Vision RFD 3D which demonstrated that the device is safe and effective, performs comparably to the

predicate devices, and is substantially equivalent to the predicate devices. Tests included verification/validation testing to internal functional specifications (including software) and non-clinical image comparisons involving flat panel display images taken with the new device and the predicate devices Ziehm Vision RFD K132904 and Ziehm Vision^2 FD Vario 3D K073346. Documentation provided demonstrates compliance of the modified device Ziehm Vision RFD 3D to all FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation tests to software requirements and software risk hazards.

Performance testing confirmed that the Ziehm Vision RFD 3D complies with 21 CFR 1020.30-32 Federal Performance Standards for X-Ray Fluoroscopic equipment and with relevant voluntary safety standards for Electrical Safety and Electromagnetic Compatibility testing, specifically IEC standards listed in the table below. Together, the verification/validation activities successfully confirmed device requirements has been fulfilled, and that system functionality is consistent with the user needs, intended uses, and the Ziehm Vision RFD 3D device correctly performs as designed, and raises no new questions regarding either safety or effectiveness. Therefore, when compared to the predicate devices the Ziehm Vision RFD 3D supports a determination of substantial equivalence to the predicate devices.

Compliance Standards:

FDA/CDRH From 3626 (5/11)	A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components.
21 CFR 1020.30-32	Federal Performance Standard for Diagnostic X-ray Systems.
MDD 93/42/EEC	Annex II of the Medical Devices Directive (MDD) 93/42/EEC
AAMI/ANSI ES60601-1	Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, mod), Date: 2010, Conformance Standard #19-5
IEC 60601-1:2005	Medical Electrical Equipment, General Requirements for Safety. Edition 3.0, Date: 2005-12-15. No Recognized Conformance Standard but general basis of AAMI/ANSI ES60601-1.
IEC 60601-1-2: 2007	Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility. Edition 3.0, Date: 2007-03-30, Conformance Standard #19-1

IEC 60601-1-3: 2008	Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment. Edition 2.0, Date: 2008-01-22, Conformance Standard #12-210
IEC 60601-2-43: 2010	Medical electrical equipment, Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures. Edition 2.0, Date: 2010-03-25, Conformance Standard #12-202
IEC 60601-2-54: 2009	Medical electrical equipment, Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy. Edition 1.0, Date: 2009-06-29, Conformance Standard #12-274
IEC 60825-1: 2007	Safety of laser products, Equipment Safety, requirements, and user guide Edition 2.0, Date: 2007-03-30 Conformance Standard #12-273
ISO 14971: 2007	Application of risk management to medical devices. Edition 2.0, Date: 2007-03-01, Conformance Standard #5-40
Conclusion:	Ziehm Imaging GmbH considers the Ziehm Vision RFD 3D to be as safe, as effective, and performs substantially equivalent to the predicate device Ziehm Vision RFD (K132904) and Ziehm Vision^2 FD Vario 3D (K073346) in accordance with its labeling.

End of 510(k) Summary

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Richard L. Westrich

Official Agent and Correspondent for Ziehm Imaging GmbH.
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